

MARKED-UP SPECIFICATION

What is claimed is:

CLAIMS

1. ~~A quality assurance system for the detection of proliferative microorganisms, comprising~~

a) ~~a system for enriching microorganisms in a sample in an "overnight culture" corresponding to 8 to 24 hours' cultivation under standard conditions according to International pharmacopoeias (for example Ph. Eur.), food laws, cosmetics directives or other commercially available indirect methods,~~

b) ~~a kit for detecting living, damaged or dead microorganisms in filterable and/or non-filterable products containing~~

~~i) at least one reagent containing an inductor and a fluorescent reagent which, with living cells, leads to the formation of a certain enzyme that releases a detectable fluorescent dye by reaction with a specific fluorescent reagent,~~

~~ii) at least one nucleic acid probe for detecting microorganisms by in situ hybridization, the nucleic acid probe being fixed to a fluorescent marker,~~

~~in which a detection limit for proliferative microorganisms of < 10 CFU/g is achieved.~~

2. ~~A quality assurance system as claimed in claim 1, characterized in that a detection limit for proliferative microorganisms of < 1 CFU/g is achieved.~~

3. ~~A kit according to claim 1, characterized in that the reagent from b i) can be used for filterable liquid samples and products or for filterable liquid parts of the samples and products to be analyzed for detecting living microorganisms and indirectly for detecting dead microorganisms.~~

4. ~~A kit according to claim 1, characterized in that the nucleic acid probe from b ii) can be used both for filterable liquid samples and products and for non-filterable samples and products and for mixtures of filterable and non-filterable samples and products for detecting living~~

MARKED-UP SPECIFICATION

microorganisms.

5. ~~— A quality assurance system as claimed in any of claims 1 to 4 for detecting gram-positive and/or gram-negative bacteria and/or yeasts and/or molds and/or algae.~~

6. ~~— The use of the quality assurance system claimed in any of claims 1 to 5 for detecting microorganisms and for the quality assessment of filterable and/or non-filterable products and for evaluating the hygiene status of production plants, a detection limit of < 10 CFU/g being achieved.~~

7. ~~— The use of the quality assurance system claimed in any of claims 1 to 5 for detecting microorganisms and for the quality assessment of filterable and/or non-filterable products selected from the group consisting of crude products, cosmetic products, pharmaceutical preparations, foods, food supplements, beverages, textile auxiliaries, detergents and dyes and lacquers.~~

8. ~~— A process for detecting microorganisms in filterable and/or non-filterable products, in which the quality assurance system claimed in any of claims 1 to 5 is used by~~

a) ~~— cultivating the samples in an "overnight culture" corresponding to 8 to 24 hours' cultivation under standard conditions according to International pharmacopoeias (for example Ph. Eur.), food laws, cosmetics directives or commercially available indirect methods in order to enrich microorganisms and~~

b) ~~— using a kit for detecting living, damaged or dead microorganisms in filterable and/or non-filterable products by~~

~~— i) — incubating the enriched sample with a reagent containing an inductor and a fluorescent reagent which induces the formation of a certain enzyme in the cells and, in the process, allows a fluorescent compound to be formed from a fluorescent reagent and/or~~

MARKED-UP SPECIFICATION

- ~~ii) after fixing the bacteria, incubating them with a nucleic acid probe which is provided with a fluorescent marker in order to induce hybridization and~~
~~detecting the fluorescence of the samples and correlating the result with the number of cells, the number of cells being determinable and, where~~
~~b) i) is used, dead and living cells being distinguishable from one another.~~

Claim 9 (new): A system for the detection of a microorganism in a sample, comprising

- a) a system for culturing a microorganism in the sample; and
- b) a kit for detecting a cultured living or dead microorganism in filterable and/or non-filterable products comprising
 - i) at least one reagent containing an inductor and a fluorescent reagent which, with living microorganisms, leads to the formation of an enzyme that releases a detectable fluorescent dye by reaction with a fluorescent reagent, and
 - ii) at least one nucleic acid probe for detecting a microorganism by in situ hybridization, the nucleic acid probe being fixed to a fluorescent marker;

in which a detection limit for a cultured microorganism of < 10 CFU/g is achieved.

Claim 10 (new): The system of claim 9, wherein the detection limit for a cultured microorganism of < 1 CFU/g is achieved.

Claim 11 (new): The system of claim 9 wherein the reagent of b) i) detects the number of living and dead microorganisms.

MARKED-UP SPECIFICATION

Claim 12 (new): The system of claim 9 wherein the nucleic acid probe of b) ii) detects the number of living microorganisms.

Claim 13 (new): The system of claim 9 wherein the sample in a) is cultured for 8 to 24 hours.

Claim 14 (new): The system of claim 13 wherein the sample in a) is cultured for 12 to 15 hours.

Claim 15 (new): The system of claim 9 wherein the presence in the sample of a gram-positive or negative bacterium, a yeast, a mold or an algae is detected.

Claim 16 (new): A process for detecting a microorganism in a sample from a filterable and/or non-filterable product, which comprises:

- a) culturing a microorganism in the sample and
- b) using a kit for detecting a living or dead microorganism from a filterable and/or non-filterable product by
 - i) incubating the cultured sample with a reagent containing an inductor and a fluorescent reagent, which induces the formation of an enzyme in the microorganism and allows a fluorescent compound to be formed from a fluorescent reagent and/or
 - ii) after fixing the microorganism, incubating with a nucleic acid probe which is provided with a fluorescent marker in order to induce hybridization;
- c) detecting the fluorescence of the sample ; and
- d) correlating the fluorescence with the number of living or dead microorganisms.

MARKED-UP SPECIFICATION

Claim 17 (new): The process of claim 16 wherein the sample is cultured for from 8 to 24 hours.

Claim 18 (new): The process of claim 17 wherein the sample is cultured for from 12 to 15 hours.